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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,754	04/11/2007	Xian-Ming Zeng	TEVE-113US	3414

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EXAMINER	
YU, HONG	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
06/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,754	ZENG ET AL.	
	Examiner	Art Unit	
	HONG YU	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-47* is/are pending in the application.

4a) Of the above claim(s) *18 and 20-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-17, 19, and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment file on 02/26/2010 is acknowledged. Claim 4 has been canceled, claims 18 and 20-46 have been withdrawn, and new claim 47 has been added. Claims 1-3, 5-17, 19, and 47 are under examination in the instant office action.

Rejections withdrawn

Applicant's amendments have overcome the claim objections and the 112 (2nd paragraph) rejections from the previous Office Action.

New ground of rejections necessitated by Applicant's amendment

Amended claims 1 recite a new limitation "particles for inhalation comprising carrier particles and particles containing active ingredient, wherein the carrier particles are bigger than the particles containing active ingredients" necessitates the following new ground of rejections.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-17, 19, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolfe et al. (US 2002/0081266 A1) in view of Ganderton et al. (US 5,254,330).

Applicant's claims

Applicants claim an inhalation composition comprising carrier particles and sufficiently smooth particles containing plurality of at least one non-crystalline drug and an excipient; wherein the active agent-containing particles are oblate spheroidal, elliptical, oval, or spherical; the excipient is soluble in conditions obtaining in the nose, lung, or mouth of a human or animal; and the carrier particles are bigger than active agent-containing particle (see claims 1-3, 5-8, 14, 15, and 19).

Claims 9-11 recite the size of the said active agent-containing particles being from 0.5 to 5 μm and from 1-3 μm.

Claim 12 recites the active agent-containing particles being uncharged.

Claim 13 recite the said active agent-containing particles being produced by spray drying.

Claims 16 and 17 recite the said at least one non-crystalline active agent being fluticasone and salmeterol xinafoate.

Claim 47 recites the carrier particles comprising a carrier selected from a group consisting of lactose and mannitol.

Determination of the Scope and Content of the Prior Art

(MPEP 2141.01)

Woolfe et al. teach a nasal inhalation composition comprising a mixture of particles of two or more amorphous drugs (such as fluticasone and salmeterol xinafoate) (claim 10, 11, and 14 and paragraph 36 and 89) and mannitol as an excipient (claim 15 and paragraph 20) produced by spray drying with smooth surface, wherein the particles are elliptical, oval, or spherical (paragraph 15).

Woolfe et al. also teach the size of the said active agent-containing particles being less than ~3 μm (paragraph 90).

Woolfe et al. teach lactose being mixed with the active agent-containing particles as a flow aid (paragraph 151).

Ascertainment of the Difference between Scope of the Prior Art and the Claims

MPEP 2141.02)

Woolfe et al. do not specifically teach: i) the active agent-containing particles having a shape of oblate spheroidal; ii) active agent-containing particles being electrically uncharged; iii) the excipient being soluble in condition obtaining in the nose,

lung, or mouth of a human or animal; iv) the carrier particles being bigger than the active agent-containing particle.

The 1st and 2nd deficiencies are addressed by the fact that the shape of the particles and the particles being electrically uncharged are inherent properties of the particles produced by the spray drying method. Since method of producing the particles taught by Woolfe et al. is the same as the method of producing the particles recited in the instant claims, the particles taught by Woolfe et al. would inherently posses the properties recited in the instant claims; having the shape of oblate spheroidal and being electrically uncharged.

The 3rd deficiency is addressed by the fact that the excipient being soluble in condition obtaining in the nose, lung, or mouth of a human or animal is an inherent property of the recited excipient. Since the excipient (mannitol) taught by Woolfe et al. is the same as the excipient (mannitol) recited in the disclosure of the instant specification (paragraph 23), mannitol taught by Woolfe et al. would inherently posses the properties of mannitol recited in the instant claims; being soluble in condition obtaining in the nose, lung, or mouth of a human or animal.

The last deficiency is cured by Ganderton et al. who teaches an inhalation composition (column 1, line 10) mixing lactose carrier particles with particle size being from 50 to 100 μm (column 2, line 6-9) with particles containing pharmacological active agent(s) with particle size being from 0.5 to 5 μm (column 3, line 32-38) for reduced agglomeration of drug particles (column 1, line 32-37).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP 2142-2143)

Woolfe et al. teach particles of the same active agents produced with the same spray drying method as that of the particles recited in the instant claims, hence the particles taught by Woolfe et al. inherently have the shape of oblate spheroidal.

It is disclosed in the instant disclosure that the particles produced with spray drying method are electrically uncharged (paragraph 12), thus the particles produced with spray drying method taught by Woolfe et al. are inherently electrically uncharged.

The excipient (mannitol) taught by Woolfe et al. is the same as the excipient (mannitol) recited in the instant disclosure of the specification (paragraph 23), thus the excipient taught by Woolfe et al. is inherently soluble in condition obtaining in the nose, lung, or mouth of a human or animal.

It would have been prima facie obvious at the time of the invention to a person of ordinary skill in the art to combine the teachings in Woolfe et al. and Ganderton et al. to mix lactose carrier particles with particle size being from 50 to 100 μm with the active agent-containing particles in the composition taught by Woolfe et al. Mixing lactose carrier particles with the active agent-containing particles with particle size smaller than that of the lactose particles to reduce agglomeration of drug particles was well known to a person of ordinary skill in the art at the time of the invention. The motivation for mixing lactose carrier particles with larger particle size with active agent-containing particles flows from lactose carrier particles with larger particle size having been mixed with active agent-containing particles to reduce agglomeration of drug particles by Ganderton et al., and from lactose flow aid having been used by Woolfe et al. It would

have been obvious to one of ordinary skill in the art to mix lactose carrier particles with larger particle size with the active agent-containing particles in the composition taught by Woolfe et al. to reduce agglomeration of drug particles.

Response to Arguments

Applicant's arguments, filed on 06/26/2010, have been fully considered but they are moot in view of new ground of rejections.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Yu whose telephone number is 571-270-1328. The examiner can normally be reached 8:50-5:20 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. Y./
Examiner, Art Unit 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616